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(54) Title: FACIAL RESPIRATOR MASK, PART AND METHOD FOR THE MANUFACTURE THEREOF

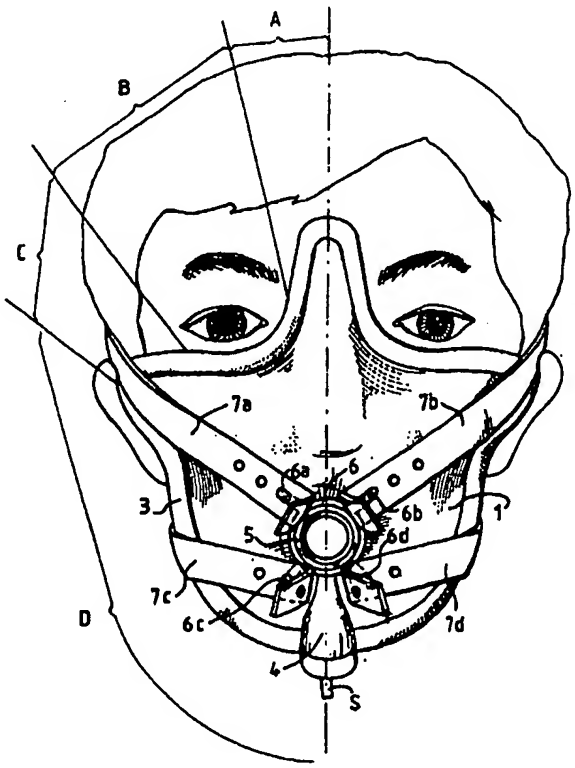
(54) Titre: MASQUE DE VENTILATION FACIAL, PIECE ET PROCEDE POUR SA FABRICATION

(57) Abstract

A facial respirator mask having a concave and rigid shell (1) with an aperture for connection to a ventilating apparatus (2), characterised in that the shape of the rigid shell (1) is arranged to encompass, in addition to the nose and mouth, the whole of the adjacent part of the face defined outwardly by the jugal bone, the temporal bone squama and the lower maxilla, so as to provide a continuous engagement between the inner surface of the shell and the bone structure of the face below the forehead. The mask may be made from a material capable of being shaped by moulding on a three-dimensional model of a human face, particularly by direct moulding on the patient's face.

(57) Abrégé

L'invention concerne un masque de ventilation facial comprenant une coque rigide concave (1) munie d'un orifice de raccordement à un apareil de ventilation (2), caractérisé en ce que la forme de la coque rigide (1) est agencée pour contenir outre le nez et la bouche, la totalité de la partie adjacente du visage définie extérieurement par l'os malaire, l'écaille de l'os temporal et le maxillaire inférieur, de manière à assurer un appui continu entre la surface interne de la coque et le relief osseux du visage en dessous du front. Ce masque peut être fabriqué à partir d'un matériau formable par modelage, sur un modèle de visage humain en relief, en particulier par modelage directement sur le visage du patient.



Facial ventilation mask, and a piece and a method for its manufacture

The present invention relates to a facial ventilation mask.

For patients requiring assisted ventilation, the facial ventilation mask, that is to say a mask covering the nose and mouth, is a non-invasive connection means which may permit a reduced risk of complications associated with the use of an endotracheal ventilation prosthesis, which complications can be, for example, laryngeal and tracheal lesions, or pneumopathies acquired under mechanical ventilation.

Assisted ventilation by means of non-invasive mechanical ventilation may be indicated, in particular, for internal pneumatic stabilization of a flail chest, in cases of respiratory problems following extubation of a patient having undergone abdominal surgery, or for the treatment of acute respiratory distress. It makes it possible to insufflate into the upper airways of the patient a gaseous mixture of (respirable) oxygen-enriched air, which penetrates into the lungs by virtue of the applied insufflation pressure being greater than the internal pressure of the respiratory system (called positive-pressure ventilation).

At present, the practitioner has at his or her disposal a standard face mask, generally supplied in different sizes. This mask consists of a rigid shell which covers the nose and mouth of the patient and which is put into place on the patient's face on either side of the wings of the nose and around the mouth, the border of the shell bearing on the bridge of the nose, at two points under the cheekbones and a zone under the lower lip, the remainder of the border being in contact with the cheeks. The rigid shell is equipped with a seal ensuring the tightness of the fit of the mask on the face. This sealing means is in most cases an inflatable rim applied on the border of the shell. Masks are also found in which the shell is equipped on the inside with

a silicone skirt which unfurls under the positive pressure so as to ensure tightness.

However, these means of ensuring the tightness of the system are not sufficiently effective under the high insufflation pressures, and problems involving leakages of the gaseous mixture are continually being encountered.

The risk of leakages with a standard mask is due to the play between the surface of the patient's face and the mask.

The risks of leakages further increase when the patient is fitted with prostheses connected to a nasal or buccal orifice, such as Salem or Drip lines. The passage of these lines between the patient's face and the edge of the mask creates play, which has an adverse effect on the tightness of the system.

It is essential to prevent leakages as far as possible. The reason for this is that the regulation of the mechanical ventilation is subject to the pressure measured at the respirator level. A leakage thus entails a risk of the respirator alarm being wrongly triggered, or of an error in the quantity of gaseous mixture being delivered, or the impossibility of stopping the insufflation of the gaseous mixture.

To counteract these leakages, it is often necessary to increase the stresses with which the system is fitted, that is to say, in general, the tensioning of the harnesses or the tightening of the straps. However, this is almost always accompanied by skin lesions, principally nasal scarring, in cases of prolonged use.

The aim of the present invention is to provide a solution to the problem of tightness of the facial ventilation mask, in such a way as to ensure efficient ventilation, while taking account of the comfort of the user and avoiding the risks of skin lesions.

Therefore, according to one embodiment of the present invention there is provided a facial ventilation mask comprising a concave rigid shell equipped with an orifice for connection to a ventilation apparatus, characterized in that the shape of the

rigid shell is designed to encompass, in addition to the nose and mouth, the whole of the adjacent area of the face as defined externally by the malar bone, the squamous portion of the temporal bone and the lower jaw, in such a way as to ensure a continuous support between the inner surface of the shell and the osseous contours of the face below the forehead.

This shape makes it possible to maintain constantly a continuous support between the inner surface of the mask and non-deformable structures constituted by the said osseous contours, independently of the possible deformations of the surface of the user's face in the area of the cheeks.

A constant hermetic contact is thus obtained between the mask and the user's face, which fact makes it possible to prevent leakages in a reliable manner, without having to apply high tightening stresses, in contrast to the use of the traditional masks which pass across the middle of the cheeks and with which a result is obtained which is far from satisfactory as regards reducing leakages.

By virtue of the advantageous shape of its shell, the mask according to the invention effectively solves the problem of tightness of ventilation, while taking into account the comfort of the user, who no longer suffers from scarring.

The connection orifice is situated in the buccal area on the shell. In this zone, the shell can have any shape permitting the fitting of tubing for the supply of respirable gas delivered by a mechanical ventilation apparatus, and permitting the passage of the said gas to the inside of the mask via the connection orifice.

According to a preferred embodiment, the shell has a protuberance in the buccal area, in which protuberance the connection orifice is formed, and such that the mouth of the user cannot be in contact with the inner surface of the shell. This makes it possible to avoid the risks of the lips or mouth pressing against the orifice in the buccal area and leading to complete or partial obstruction of the ventilation orifice.

The mask can advantageously comprise a piece for connection to a mechanical ventilation apparatus, this piece being fitted on the connection orifice.

The piece for connection to a ventilation apparatus is in this case a rigid piece, having a tubular part, allowing the mask to be fitted with tubing for the supply of oxygen or a gaseous mixture of oxygen and air, and being sufficiently strong to withstand without damage the manipulation of the gas supply tubing. The tubular part of the connection piece is arranged projecting from the outer surface of the shell in the area of the connection orifice.

The connection piece advantageously has, at one end of the tubular part, called the inner end and situated towards the patient, a flange which extends radially around the tubular part and bears on the inner surface of the shell.

In a particularly advantageous embodiment, the flange has a concavity which is oriented in the same direction as the concavity of the shell. In particular, the flange can have a truncated spherical cap shape.

Such a connection piece, which also forms the subject of the present invention, thus fits easily on the concave shell, creating a relatively uniform support of the flange on the inner surface of the shell. In addition, because of its concavity, the flange defines a volume between the user's mouth and that end of the tubular part situated inside the mask, in such a way that the risks of obstruction of the ventilation orifice are limited.

Such a connection piece is also advantageously fitted on a rigid shell provided with a protuberance in the area of the connection orifice, such as has been described hereinabove.

It is also advantageous for the tubular part of the connection piece to have an internal cross-section which is wider at its end farthest from the shell.

The facial ventilation mask according to the invention preferably comprises, over all or part of the

inner surface of the shell, a sealing means, particularly at the border of the shell. The seal makes it possible to perfect the tightness of the contact between the mask and the user's face, and to afford greater comfort for the user in the area of the bearing surfaces of the mask. This seal can advantageously be in the form of an expanded material, in particular a foam.

In a specific embodiment of the ventilation mask for a patient fitted with a line connected to a nasal or buccal orifice, the shell includes, in the area of the central part of the lower jaw, a bulge projecting from its outer surface and forming an inner sheath which is intended to permit the passage of the line outside the mask.

This sheath, the inner surface of which is lined completely with sealing means, forms a projecting fold in the shell, inside which fold one part of the surface of the said seal comes into contact with the complementary part in such a way that the inner volume of the sheath is taken up completely by the sealing means. The sheath can thus be considered as a solid element which is not capable of adversely affecting the tightness of the system. An element such as a line can be inserted into the said sheath in the fold of the sealing means, compressing the latter in an elastic manner, the whole arrangement remaining completely hermetic. The sheath acts as a hermetic airlock allowing the line to exit the mask without disrupting the continuous contact between the inner surface of the mask and the osseous contours of the patient's face.

The facial ventilation mask according to the invention can be equipped with means for holding it in place on the user's face. These means can be chosen from among the known conventional means, such as rubber harnesses or tightening straps fixed on the mask so as to exert a restoring force between the shell and the user's head, which force is sufficient to maintain the hermetic contact, although not so great as to inconvenience the user, and to ensure a tight and comfortable ventilation

system. During the tightening, the sealing means is compressed between the osseous contours of the face and the rigid shell, in a uniform manner over all of the osseous contours.

These means are preferably fixed on the mask in the area of the connection zone.

In order to prevent leakages, the elements constituting the mask (shell, connection zone, sealing means) must be made of materials which are not permeable to air. Moreover, they must be biocompatible, that is to say well tolerated by the facial skin and by the upper airways.

For the shell, plastic materials which combine strength and lightness are preferred. In particular, use is advantageously made of polycaprolactone polymers or mixed transpolyisoprene/polycaprolactone copolymers.

The connection zone, in particular the connection piece, must be made of a material which is sufficiently tough to withstand the connection to the ventilation apparatus. Use is advantageously made of tough polymer materials such as polyvinyl chloride or polytetrafluoroethylene.

The sealing means is advantageously made of polyvinyl chloride foam.

According to another embodiment the present invention relates to a method for manufacturing a facial ventilation mask,

characterised in that the concave rigid shell is formed from a material which can change between a plastic phase and a rigid phase, by modelling the said material in its plastic phase, on a three-dimensional model of a human face, in such a way as to take an impression of the contours of the nasal bone, the malar bones, the squamous portions of the temporal bones and the lower jaw, then by rigidifying the said material in situ on the three-dimensional model.

Among the standard materials having the required qualities set out hereinabove, it is preferable to use the polymer materials which are thermoformable at low

temperature, that is to say at a temperature below 70°C, in particular below 60°C, especially polycaprolactones or transpolyisoprene/polycaprolactone copolymers.

By having at one's disposal a range of models possessing the average anatomical characteristics of categories of individuals of defined type, sex and age, it is possible to manufacture masks which are adapted to the individuals of these different categories.

The method of manufacture generally comprises the successive steps of:

(a) cutting out a piece of the said material to the dimensions of the model, in a shape spreading over the surface of the area of the face delimited by the nasal bridge, the malar bones, the squamous portions of the temporal bones and the lower jaw, and

(b) shaping the said piece by modelling the piece of material in its plastic phase on the three-dimensional model, taking an impression of the contours of the abovementioned bones,

(c) rigidifying the modelled material, in situ on the model, in order to form the rigid shell (1),

and (d) forming an orifice in the buccal area, either on the piece before it is shaped, or on the rigidified shell.

During the modelling step (b), a protuberance can be formed in the buccal area on the shaped shell, thus creating a free space between that zone of the model extending around the mouth and the piece of formable material.

When it is intended to manufacture a ventilation mask possessing a connection orifice equipped with a connection piece projecting from the shell of the mask, the method comprises a step which involves positioning the said connection piece in the connection orifice, before or after step (b), as appropriate.

For the user's comfort, the connection piece possessing a part which is intended to be arranged inside the shell, in particular a flange intended to bear on the inner surface of the shell, is advantageously arranged in

such a way that this part does not protrude from the inner surface of the shell after it has been placed in the mask. In this respect, it is preferable to equip the piece of material with the connection piece before it is shaped on the three-dimensional model. The rigid shell then assumes a shape which takes account of the connection piece, so that the inner surface of the mask is relatively uniform.

Similarly, the sealing means can be applied either on the rigid shell after modelling, or on the piece before modelling. The second possibility is preferred insofar as it makes it possible to give the shell, during modelling, a shape which takes account of the elements which are situated inside the final mask ready for use. This is particularly advantageous when the mask possesses sealing means over the whole of its inner surface, in such a way as to avoid the loss of internal volume of the mask due to the thickness of the seal. The mask then remains perfectly adapted to the anatomical type of the model, so as to offer the user improved comfort.

The seal can be attached by adhesive bonding, in particular. The seal is preferably self-adhesive and consists of a layer of expanded material, particularly foam, and an adhesive layer.

This method of manufacture makes it possible to produce various models of facial ventilation masks in accordance with average anatomical characteristics pertaining to various categories of individuals, and affording the advantages of use which have been described hereinabove.

The method can also be applied on a case-by-case basis, for individuals for whom the average anatomical characteristics are not suitable or are poorly suited, by carrying out the operation of modelling of the shell directly on the face of the user.

It is thus possible to optimize the shape of the shell of the mask for patients of particular morphology by modelling, on the patient's face, the piece which has

been pre-cut to the dimensions of the model. With a range of models possessing the average characteristics of predefined categories of individuals, it is thus possible to manufacture a range of stencils for cutting out the piece, or else a range of pre-cut pieces which can be adapted to the individuals of these different categories.

For patients who are even more atypical, it is possible to cut the said piece directly to the measurements of the patient's face.

In both these cases, it is expedient to form a connection orifice in the buccal area in the piece of formable material before it is applied to the user's face, in order to allow the user to breathe normally during the whole modelling operation.

The modelling is advantageously carried out so as to take an exact impression of the area of the user's face as delimited by the nasal bridge, the malar bones, the squamous portions of the temporal bones and the lower jaw.

The mask thus manufactured, and matching perfectly the contours of the user's face, makes it possible to optimize the control of the ventilation by avoiding the leakages at the border of the mask and the creation of dead volume as a result of the puffing of the cheeks.

The flexible structures of the face, which the cheeks represent, are in fact encompassed within the mask and are in contact with the inner surface of the latter. During ventilation, the cheeks are able to puff out only to a limited extent under the effect of the positive pressure, and thus press against the rigid shell of the mask, so as to ensure an even tighter contact, the restriction on the puffing of the cheeks limiting the dead space.

In addition, the wide contact surface between the mask and the user's skin makes it possible to achieve low support pressure stresses, given that the pressure which is exerted there is inversely proportional to the contact surface.

The present invention will be illustrated by the example hereinafter which describes a facial ventilation mask for a patient fitted with a nasogastric line of the Salem line type, as well as the manufacture of this mask by modelling on the face of the patient.

In the course of the description reference will be made to the attached drawings, in which:

- Figure 1 represents a frontal view of a facial ventilation mask;

- Figure 2 represents a right-side profile view of the same mask, with part cut away to illustrate a vertical section of the mask on the axis of the nose;

- Figure 3 represents a horizontal section of the central part of the mask in the area of the chin and illustrates the passage of the nasogastric line;

- Figures 4A and 4B are a top view and a longitudinal cross-section, respectively, of a piece for connection to a ventilation apparatus;

- Figure 5 shows the shape of a flat stencil made to the measurements of the patient's face.

The facial ventilation mask represented in Figures 1 and 2 comprises a rigid shell, symmetrical with respect to the vertical median axis of the user's face. This shell includes a connection orifice 2 in the buccal area. The perimeter of the shell is symbolized in these figures by a flap of the sealing means 3 which extends over the whole of the inner surface of the shell.

The shape of the shell 1 is designed to rest on the osseous contours of the patient's face in a continuous manner. The perimeter of the shell can thus be divided from the nose to the chin in 4 contiguous sections A, B, C and D, which are symmetrical with respect to the median axis of the face. Section A follows the contours of the nasal bone proper, from the nasal bridge to the base of the lateral parts of the nasal bone proper, behind the wings of the nose; section B follows the malar bone in the suborbital region; section C follows the squamous portion of the temporal bone up to the temporomandibular articulation, but without reaching

it; and, finally, section D follows the lower jaw, down along the ascending branch of the jaw, crossing the body of the lower jaw in front of the right mandibular angle, and finally following the inferior margin of the body of the lower jaw beneath the chin.

The surface of the shell 1 has a continuous support on the nasal bone in the zone adjacent to the edge in the area of section A, the cheekbone in the zone bordered by section B, and the cheek in the zone bordered by sections C and D. The shell includes a protuberance in the area of the connection orifice 2, which forms a free space E between the patient's mouth and the inner surface of the shell.

The line S connects the patient's stomach to an external feed source passing via the nose. Inside the mask it passes to the side of the mouth so as not to constitute an obstruction in the area of the lips.

To permit the passage of the line S out of the mask, the shell 1 comprises, in the central part of the lower jaw, in the area of the furrow of the patient's chin, a bulge 4 perpendicular to the connection orifice 2 and descending to the lower edge of the shell 1, forming on the inside a vertical sheath for the line. Like the remainder of the inner surface of the shell 1, the projection 4 is lined completely with sealing means.

As Figure 3 shows, in the area of the projection 4 the inner surface of the shell follows the body of the lower jaw up to the area of point F, where it diverges away from the patient's face so as to form a tubular excrescence which is symmetrical in relation to the vertical median axis of the mask, and rejoins the body of the lower jaw in the area of point F', symmetrical to F in relation to this median axis. The space situated between the points F and F' is filled completely by the presence of the sealing means 3, which is folded back on itself.

Inside the sheath, the seal 3 is lightly compressed between the line S and the rigid shell 1.

The passage of the line S out of the mask is thus

ensured in a completely sealed manner, the sheath-forming projection 4 acting as a hermetic airlock.

The use of a material which is thermoformable at low temperature, such as polycaprolactone, is advantageous because it leads to formation of a shell which is semi-rigid, that is to say slightly deformable. In this case, a slight deformation of the shell in the area of the bulge 4 allows the line to be disengaged very easily when it is necessary to reposition the mask or remove the mask temporarily or definitively. The replacement of the line is just as easy, by means of a slight deformation of the shell in the area of the projection.

The sealing means 3 which is applied over the whole of the inner surface of the shell 1 is turned back onto the outer surface in such a way as to separate the edge of the shell from the patient's face. This affords a pleasant feel around the whole perimeter of the mask, guarantees the patient's comfort when it is being placed on the patient's face, and prevents the risks of cutting or injury which are occasioned when the skin of the face bears on the edge of the shell.

A connection piece 5 is positioned in the connection orifice 2. In Figures 4A and 4B it is represented on a slightly enlarged scale for reasons of clarity. It possesses a tubular part 5a and a concave flange 5b. The tubular part 5a has a cylindrical external shape and a truncated internal shape, the internal diameter at the end where the flange is situated being smaller than the internal diameter at the connection end.

The tubular part 5a possesses, at its end, a flange with a truncated spherical cap shape. The dimensions of such a piece can be, for example, in the case of the tubular part 5a, of the order of 2.6 cm for the external diameter, 2.2 cm for the internal diameter at the end opposite the flange, and 2 cm for the internal diameter in the area of the flange.

The sphere on which the inner surface of the flange 5b rests has a radius of approximately 4.5 cm. The flange rests on this sphere via a truncated cap surface,

the large diameter of which is approximately 4 cm, while the small diameter corresponds to the small internal diameter of the tubular part 5b, i.e. 2 cm.

The flange 5b is arranged bearing on the inner surface of the shell 1. It can be joined to the latter particularly by adhesive bonding using a thermoformable material which is compatible with the materials constituting the piece 5 and the shell 1.

In general, according to the shape of the connection piece 5, it is possible to envisage very different modes of fixing.

A ring with hooks 6 is fitted on the tubular part 5a of the piece 5. It is in the form of a flat ring whose internal diameter corresponds to the external diameter of the connection piece 5, equipped with four hooks 6a, 6b, 6c and 6d projecting from the plane of the ring.

A harness 7 with four elastic belts 7a, 7b, 7c and 7d allows the mask to be held in place on the patient's face. Each belt is provided with fastening holes and is fixed to the ring 6 by inserting a hook in one of the holes provided on the said belt. The four belts join, at the end opposite the one pierced with holes, to form a surface which is placed behind the patient's head.

The positioning of the mask on the patient's face is adapted by adjusting the point of attachment of each of the belts 7a to 7d on the hooks 6a to 6d of the ring 6. The restoring force exerted by the belts hold the mask firmly on the patient's face.

The method for manufacturing this mask is as follows:

In a first stage, a flat stencil is produced from a flexible sheet of transparent plastic, cut to the measurements of the patient's face and following the osseous contours situated below the forehead. The stencil, represented in Figure 5, is symmetrical with respect to its median vertical axis and its outline can be divided into 4 contiguous sections G, H, I and J.

Once applied on the patient's face, the stencil

covers the surface of the nose from the nasal bridge to the base of the nasal bone along the section G, the cheekbone along the section H, and extends up to the temporomandibular articulation along the section I. It also covers the cheek and half of the chin over the remainder of its surface bordered by the section J, which follows the inferior margin of the body of the lower jaw under the contours of the chin, a finger's breadth behind the latter.

A hole K is pierced at the position of the mouth on the stencil. The shape and the dimensions of the hole K are a function of the shape and the dimensions of the connection piece 5.

A piece P following the outline of the stencil is cut from a sheet of rigid polycaprolactone, approximately 3 mm in thickness, marketed by the company Fish under the trade name "AQUAPLAST". The outline of the piece P, identical to that of the stencil, can thus be divided into sections G to J in the same manner. The outline of the hole K is plotted, indicating the position of the buccal orifice which will subsequently be pierced. Alternatively, the buccal orifice can be pierced at this stage of the operations.

The piece P is immersed in a bath of water thermostated at 60°C until it has softened sufficiently. The piece is withdrawn from the bath, it is dried on a cloth, and the buccal orifice is pierced on the hot piece P, following the outline of the hole K.

Polycaprolactone which is thermoplastic at 60°C is very advantageous since it remains plastic over a wide temperature range to 30°C. After it has been cooled sufficiently to be applied directly on the patient's face without risk of burning, it can still be readily modelled. All other thermoplastic materials which remain plastic at temperatures sufficiently low for the application to the skin to remain tolerable can be used advantageously. Other examples which may be mentioned are transpolyisoprene/polycaprolactone copolymers.

The connection piece 5 is then put into place by

passing the tubular part 5a through the buccal orifice, the flange 5b bearing on a surface of the piece P which will be referred to hereinafter as the inner surface of the piece P.

A sheet of sealing means 3 made of self-adhesive polyvinyl chloride foam is then applied on the inner surface of the hot piece P, the said sheet having been cut roughly to dimensions greater than those of the transparent plastic stencil, and pierced with a hole at the site of the buccal orifice indicated on the stencil. The self-adhesive seal is placed in such a way as to bring the buccal orifices into alignment.

It is advantageous to choose a seal such that the adhesive has good heat compatibility with the thermoformable material. In addition, the piece having been heated by immersion in a water bath, it is preferable to choose an adhesive which is able to establish effective union in the presence of traces of water remaining after drying.

Alternatively, the seal can be applied on the inner surface of the shell after the shaping of the piece P.

According to another alternative, the seal can be applied only in the area of the perimeter of the piece P, or else can be applied subsequently on the shaped shell 1 in order to line the edge of the shell.

The piece of thermoformable material P, equipped with the connection piece 5 and covered on its inner surface with the seal 3, is applied to the user's face, from the side of the seal 3, while its temperature is high enough to allow the material to be shaped and has sufficiently lowered so that the application of the piece to be shaped to the user's face does not cause the user to be burned. The piece P is positioned in such a way that its outline coincides with the bone structures marked for tracing the stencil. The assembly is shaped by modelling in such a way as to take an impression of the contours of the patient's face, so that the shell 1 matches perfectly the shape of that area of the patient's

face delimited by the outline of the piece P. The perimeter of the shaped shell 1 is divided into sections A to D, such as described hereinabove, which correspond to the sections G to J of the outline of the flat piece P.

During the modelling, a slight traction is exerted on the connection piece 5, in the direction away from the patient's face, in order to draw the peribuccal zone of the piece P in this direction and thereby to form a protuberance which creates the free space E between the patient's mouth and the inner surface of the mask. The concave shape of the flange 5b of the connection piece 5 is very advantageous for drawing the softened material without risk of tearing, and at the same time gives the protuberance the corresponding concavity.

Moreover, this pulling makes it possible to integrate the connection piece 5 in the shell 1, with the inner surface of the flange 5b and the inner surface of the shell 1 forming a continuous surface.

The bulging shape 4 is also produced during the operation of modelling of the plastic material. The line S being passed in front of the patient's face in order to form a free space between the line and the chin, that part of the piece P situated below the connection orifice 2 is modelled around the line. By pinching the material between the line and the chin, the piece is folded back on itself around the line, and a pressure is exerted which is sufficiently great to ensure that the mutually facing surfaces of the sealing means 3 come into contact with each other. The contact is maintained throughout the shaping operation.

The shaped piece is kept on the user's face until it rigidifies as a result of the cooling of the thermoformable material. The total duration of the shaping operation is approximately 5 to 10 minutes.

During the modelling and rigidifying operations, the buccal orifice is maintained in the area of the patient's mouth, ensuring a permanent air intake which allows him to breathe normally. The buccal orifice, equipped with the connection piece, can also be used to

introduce an oxygen connector and to increase the inspiratory fraction of oxygen (O_2IF) during the shaping step.

The shell is then removed from the patient's face, and the connection piece is adhesively bonded to the inner surface of the shell 1.

A conventional thermoformable material is preferably used to perform the adhesive bonding. The adhesive is advantageously applied in excess on the inner surface of the mask, on and around the flange of the buccal piece, in such a way as to obtain at this location a uniform inner surface free from roughness.

The securing means are then fixed in place on the body of the shell thus manufactured. The ring with four hooks 6 is fitted on the tubular part 5a of the connection piece, and one of the four belts 7a, 7b, 7c and 7d of a rubber securing harness 7 is attached to each of the four hooks 6a, 6b, 6c and 6d.

The mask thus manufactured is placed on the patient's face in order to provide a completely tight ventilation system.

Alternatively, it is possible to manufacture a facial ventilation mask for a patient fitted with a small-diameter line, such as a Salem or Drip line, connected to a nasal or buccal orifice, the shell of which mask includes, instead of the bulge constituting a sheath 4, an orifice which is equipped with an elastomeric feed-through sleeve fitted on the said orifice so as to receive the line. The internal diameter of the feed-through sleeve is calibrated as a function of the external diameter of the line, in order to guarantee the tightness of the contact.

The orifice can be pierced on the piece P before it is has been shaped, either softened or unsoftened, or else on the shell 1 which has been shaped by modelling and rigidified.

Although the present invention has been described more precisely in the specific case of the mechanical ventilation of patients, particularly in resuscitation or

respiratory assistance, it can also be exploited in all other applications of mechanical ventilation. For example, the facial mask, such as it has been described above, can be used by a fighter pilot. The particular configurations of the shell, such as bulged sheaths or feed-through holes, can in these cases be made use of for incorporating various accessories in the ventilation mask.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Facial ventilation mask comprising a concave rigid shell equipped with an orifice for connection to a ventilation apparatus, characterized in that the shape of the rigid shell is designed to encompass, in addition to the nose and mouth, the whole of the adjacent area of the face as defined externally by the malar bone, the squamous portion of the temporal bone and the lower jaw, in such a way as to ensure a continuous support between the inner surface of the shell and the osseous contours of the face below the forehead.

2. Facial ventilation mask according to Claim 1, characterized in that the connection orifice is equipped with a connection piece possessing a tubular part, the tubular part projecting from the outer surface of the shell.

3. Facial ventilation mask according to Claim 2, characterized in that the connection piece additionally possesses, at one of the ends of the tubular part, a flange extending radially around the tubular part and bearing on the inner surface of the shell.

4. Facial ventilation mask according to Claim 3, characterized in that the flange has a concavity oriented in the same direction as the concavity of the shell, and in particular has a truncated spherical cap shape.

5. Facial ventilation mask according to any one of Claims 1 to 4, characterized in that the shell has a protuberance in the buccal area, in which protuberance the connection orifice is

formed, such that the mouth of the user cannot be in contact with the inner surface of the shell.

6. Facial ventilation mask according to any one of Claims 1 to 5, characterized in that it comprises, over all or part of the inner surface of the shell, a sealing means, in particular made of expanded material.

7. Facial ventilation mask according to any one of Claims 1 to 5, characterized in that the shell includes, in the area of the central part of the jaw, a bulge projecting from its outer surface and forming an inner sheath, the inner surface of which is lined completely with sealing means, and inside which the said seal is folded back on itself, the mutually facing sealing surfaces forming a hermetic contact.

8. Method for manufacturing a facial ventilation mask, characterized in that the concave rigid shell is formed from a material which can change between a plastic phase and a rigid phase, by modelling the said material, in its plastic phase, on a three-dimensional model of a human face, in such a way as to take an impression of the contours of the nasal bone, the malar bones, the squamous portions of the temporal bones and the lower jaw, then by rigidifying the said material in situ on the three-dimensional model.

9. Method according to Claim 8, characterized in that it comprises the successive steps of:

(a) cutting out a piece of the said material to the dimensions of the model, in a shape spreading over the surface of the area

of the face delimited by the nasal bridge, the malar bones, the squamous portions of the temporal bones and the lower jaw,

(b) shaping the said piece by modelling the material in its plastic phase on the three-dimensional model, taking an impression of the contours of the abovementioned bones, and

(c) rigidifying the modelled material, in situ on the model, in order to form the rigid shell, and

(d) forming a connection orifice in the buccal area, either on the piece before it is shaped, or on the rigidified shell.

10. Method according to Claim 8 or 9, in which the said material is a material which can be thermoformed at a temperature below 70°C, the cut-out piece of thermoformable material being heated to a temperature permitting the softening of the said material in its plastic phase, prior to step (b), the shaping of the piece in step (b) comprising modelling the plastic material on the model and rigidifying the shaped shell by cooling it in situ on the model.

11. Method according to Claim 10, in which step (d) takes place before step (b), and the piece of thermoformable material is heated between step (a) and step (d).

12. Method according to any one of Claims 8 to 11, in which, during step (b), a protuberance is formed in the buccal area on the concave shell, thus creating a free space between that zone of the face of the model extending around the mouth and the piece of formable material.

13. Method according to any one of Claims 8 to 12, additionally comprising the positioning of a sealing means, in particular a self-adhesive foam, over all or part of the inner surface of the piece of formable material, before or after step (b).

14. Method according to any one of Claims 8 to 13, for the manufacture of a mask for a patient fitted with a line connected to a nasal or buccal orifice, in which method, during step (b), a bulge projecting from the outer surface of the shell is formed at the border of the said shell, creating an inner sheath for the said line, by pinching the formable piece around the said line.

15. Method according to any one of Claims 8 to 14, in which the connection orifice is formed on the piece before step (b), then a connection piece comprising a flange is put into place by positioning the said flange in contact with a surface of the piece of material corresponding to the inner surface of the shell, then proceeding to the modelling step (b).

16. Method according to any one of Claims 8 to 15, characterized in that the shaping operation in step (b) is carried out by modelling directly on the face of the patient.

17. A facial ventilation mask and a method for its manufacture substantially as hereinbefore described with reference to Figures 1 to 3.

DATED this 27th day of May, 1999

Assistance Publique-Hopitaux De Paris

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Facial ventilation mask, and a piece and a method for its manufacture

ABSTRACT

The invention relates to a facial ventilation mask comprising a concave rigid shell (1) equipped with an orifice for connection to a ventilation apparatus (2), characterized in that the shape of the rigid shell (1) is designed to encompass, in addition to the nose and mouth, the whole of the adjacent area of the face as defined externally by the malar bone, the squamous portion of the temporal bone and the lower jaw, in such a way as to ensure a continuous support between the inner surface of the shell and the osseous contours of the face below the forehead.

This mask can be manufactured from a material which can be shaped by modelling on a three-dimensional model of the human face, in particular by modelling directly on the face of the patient.

Fig. 1

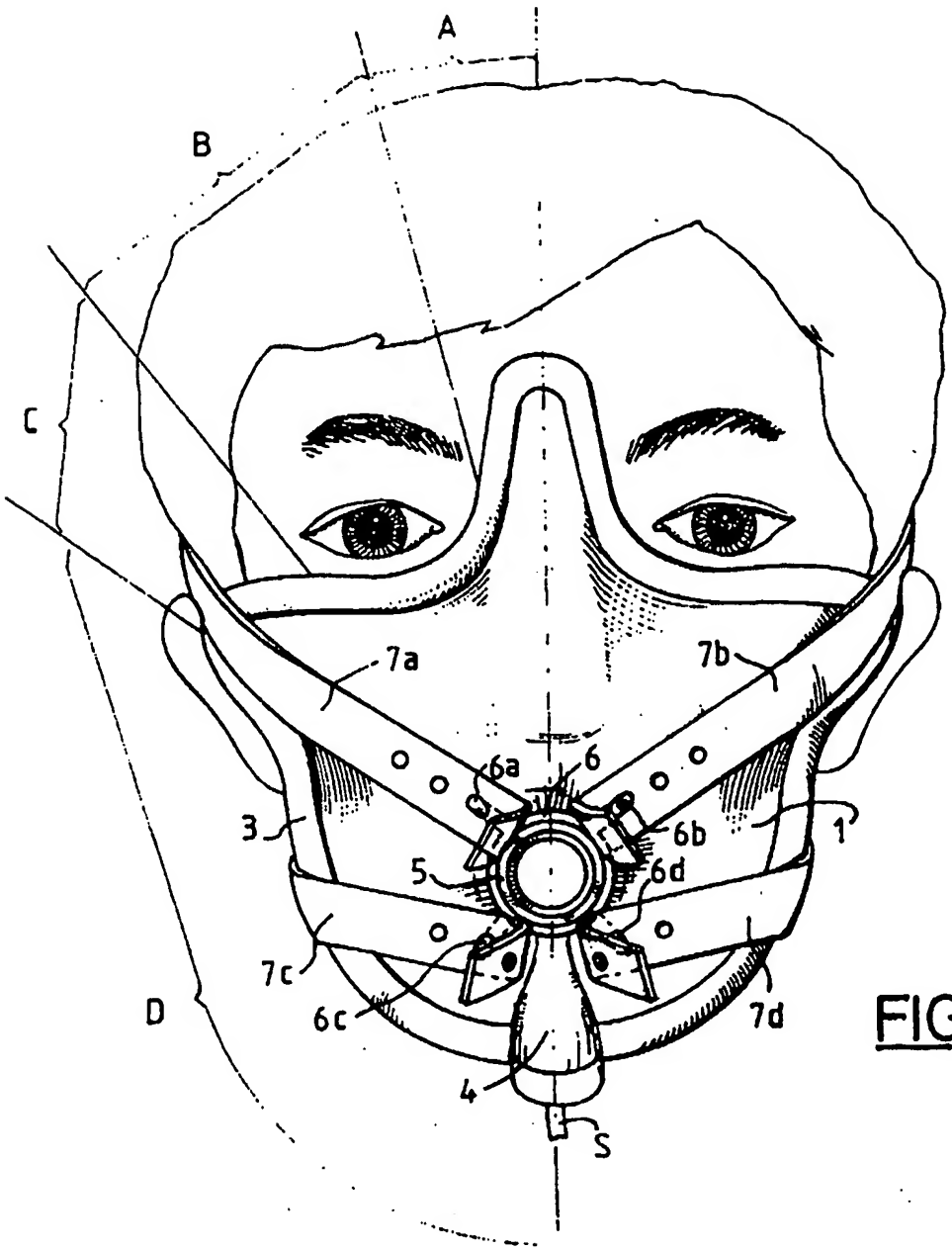

FIG. 1

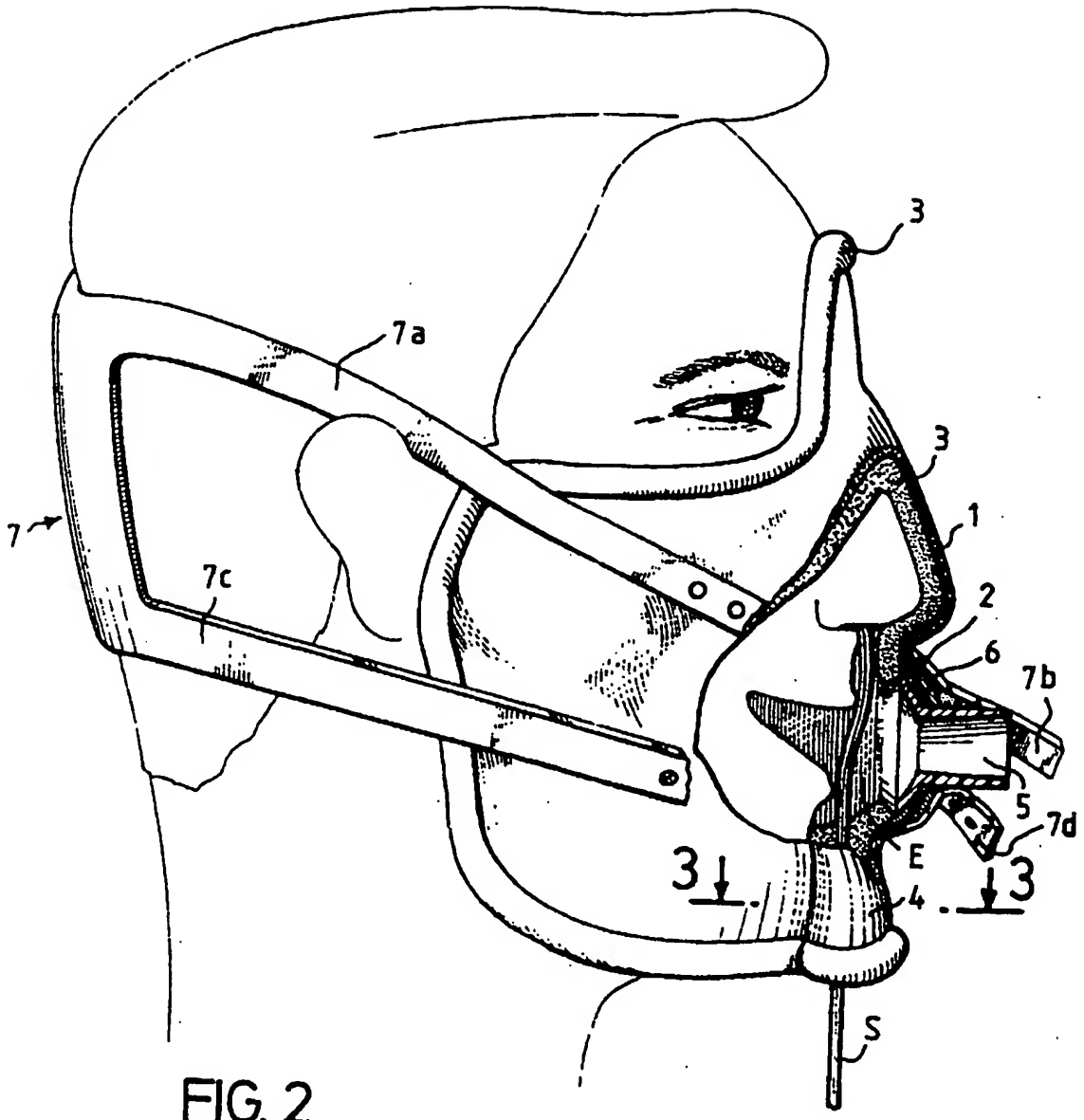

FIG. 2

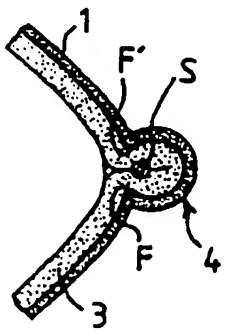

FIG. 3

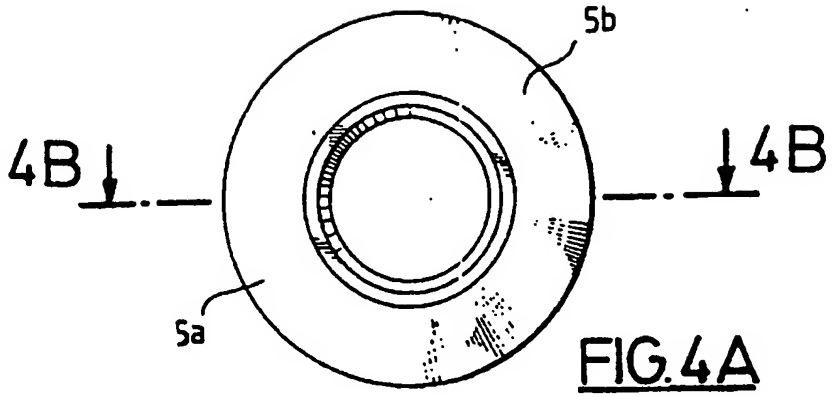

FIG.4A

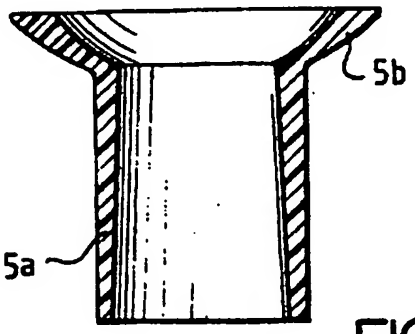

FIG.4B

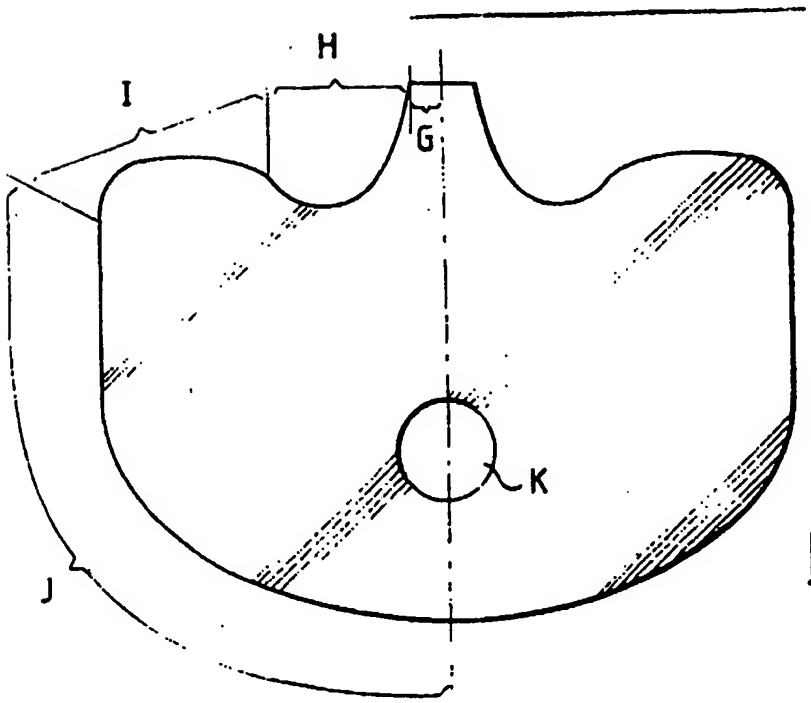

FIG.5